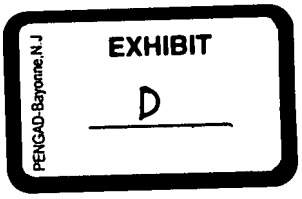
A. IDE No. G940155 - Submissions to FDA and Responses Through FDA Approval.

10/28/94	IDE application submitted to FDA by Gynecare, Inc.
11/02/94	FDA Notice of IDE No. G940155 assigned for EASY(TM) ENDOMETRIAL ABLATION SYSTEM (effective November 30, 1994).
09/05/95	Amendment to IDE No. G940155 submitted for performing efficacy study of the Gynecare Uterine Balloon Therapy (UBT) System in comparison with Rollerball Endometrial Ablation.
09/25/95	Supplemental Application submitted to IDE No. G940155 updating sections of revised protocol in response to September 21, 1995, conference call of Mr. Pollard of the FDA.
10/02/95	Supplemental application submitted to update "Other Institutions" section of IDE No. G940155.
10/05/95	Response of FDA granting conditional approval of efficacy and safety clinical study for the UBT.
02/23/96	Response of FDA approving proposed investigational plan and protocol changes.
03/31/97	Pre-PMA submission for ThermaChoice™ Uterine Balloon Therapy (UBT) System.

B. PMA No. 970016 - Submissions to FDA and Responses Through FDA Approval.

05/21/97	Fax inquiry and comments from FDA concerning outstanding issues on preliminary review of PrePMA submission of 03/31/97.
06/16/97	Formal premarketing approval (PMA) application submitted by Gynecare, Inc. for ThermaChoice™ Uterine Balloon Therapy Device and response to FDA facsimile of 05/21/97.



08/11/97	PMA amendment submitted in response to FDA telephone calls of 08/08/97 concerning manufacturing instructions, quality assurance procedures and testing matters.
08/29/97	PMA amendment submitting interim update Table of Contents.
10/06/97	Panel Hearing.
10/10/97	Post panel letter from FDA and notice of deficiency discussed in teleconference of 10/1/97.
10/16/97	Followup response to FDA teleconference of 10/16/97 concerning engineering tests and clinical aspects.
10/17/97	Response to deficiency set forth in 10/10/97 letter submitted.
10/20/97	Followup response to FDA teleconference of 10/08/97 concerning software validation issues in letter of 10/10/97.
10/21/97	Followup response to FDA teleconference of 10/21/97 concerning engineering test data sent 10/16/97.
10/31/97	PMA amendments submitted to comply with FDA panel conditions in status letter of 10/10/97.
11/25/97	Supplemental amendment notifying FDA of merger of Gynecare, Inc./Ethicon, Inc. on November 20, 1997.
12/10/97	Copy of final labeling changes submitted in response to FDA teleconference of 12/10/97.
12/12/97	PMA approved by FDA to Gynecare, Inc./Ethicon, Inc.
12/31/97	PMA amendments and submission of two copies of final labeling to comply with conditions of approval.